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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/431,469 11/01/99 ARMISTEAD

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HM22/0620

EXAMINER

MORAN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/431,469

Applicant(s)

ARMISTEAD ET AL.

Examiner

Morjorie Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 11.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *detailed action*.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All rejections and objections not repeated below are hereby withdrawn.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to a process (method of evaluation); however, claims 19 and 23 recite only steps of computation and analysis.

As set forth in MPEP 2106, "The claimed invention as a whole must produce a "useful, concrete and tangible" result to have a practical application. A process that consists solely of the manipulation of an abstract idea is not concrete or tangible. See *In re Warmerdam*, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). See also *Schrader*, 22 F.3d at 295, 30 USPQ2d at 1459", and "... a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process. In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a "mathematical algorithm"); or
- simply manipulate abstract ideas, e.g., a bid (*Schrader*, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (*Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application. "

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The computation and analysis steps of claims 19 and 21 are mathematical operations, and the claims do not recite any concrete or tangible results, therefore the claims do not recite statutory subject matter.

### ***Claim Objections***

Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 20 recites a set of structure coordinates which is broader in scope than the set recited in parent claim 19. Specifically, amino acids 253, 256, 284, 312, and 317 are recited in claim 19 but not in claim 20.

### ***Claim Rejections - 35 USC § 112***

Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation "said molecule or molecular complex" in line 2. There is insufficient antecedent basis for this limitation in the claim, therefore the claim is indefinite. Parent claim 22 recites a *crystallized* molecule or molecular complex. It is noted that claim 23 is intended to limit the entire complex to be that defined by the structure coordinates of Figure 1, wherein any homologue thereof is limited as recited in claim 23, as argued by the attorney in an interview (See the Interview Summary of 6/18/01), therefore claim 23 further limits claim 22. In order to further clarify the limitations of the claim and overcome the rejection set

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forth above, the examiner recommends inserting --crystallized-- before "molecule" in line 2;  
AND replacing "a set of" with --all of the-- or by replacing "a" with --the entire-- in lines 2-3.

Amended claim 24 is still not commensurate in scope with the teachings of the specification. The specification provides support on pages 12, 31 and 35 for particular combinations of CnA, CnB, FKB12 and FK506 residues. None of the combinations taught by the specification are those recited in amended claim 24, therefore claim 24 is again rejected.


### **Conclusion**

Claims 19-24 are rejected, but appear to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a Patent Analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
~~GROUP 1800~~  
H41631

Marjorie A. Moran  
June 18, 2001